

**CHAPTER 75-09.1-10**  
**LICENSING AND TREATMENT STANDARDS FOR OPIOID TREATMENT**  
**PROGRAMS**

Section	
75-09.1-10-01	Definitions
75-09.1-10-02	Requirements for Opioid Treatment Program License - Application
75-09.1-10-03	Denial of Application for Opioid Treatment Program License
75-09.1-10-04	Issuing License to Opioid Treatment Program
75-09.1-10-05	Suspension and Revocation of License - Appeal
75-09.1-10-06	Subsequent Licensing Inspection and Review
75-09.1-10-07	Opioid Treatment Program Requirements
75-09.1-10-08	Care of Adolescents in Opioid Treatment Program
75-09.1-10-09	Treatment
75-09.1-10-10	Opioid Treatment Program Administrative Organization and Responsibilities
75-09.1-10-11	Facility and Clinical Environment
75-09.1-10-12	Risk Management
75-09.1-10-13	Opioid Treatment Program Closure
75-09.1-10-14	Diversion Control
75-09.1-10-15	Medical and Behavioral Standards

**75-09.1-10-01. Definitions.** In this chapter, unless the context or subject matter otherwise requires:

1. "Accreditation" means the process of review and acceptance by an accreditation body.
2. "Accreditation body" means a body that has been approved by the administration under title 42, Code of Federal Regulations, part 8 to accredit opioid treatment programs using opioid agonist treatment medications.
3. "Administration" means the substance abuse and mental health services administration of the United States department of health and human services.
4. "Certification" means the process by which the administration determines that an opioid treatment program is qualified to provide opioid treatment under federal opioid treatment standards.
5. "Certification application" means the application filed by an opioid treatment program for purposes of obtaining certification from the administration, as described in title 42, Code of Federal Regulations, part 8.
6. "Center" means the center for substance abuse treatment within the administration which promotes the quality and availability of

community-based substance abuse treatment services to which the administration has delegated certain responsibilities for the certification of opioid treatment programs.

7. "Critical incident" means an event that could have a negative impact on a patient, a patient's family members, or the opioid treatment program or its staff, including an event that involves the loss of life or function, a serious physical or psychological injury, and a medication error.
8. "Detoxification treatment" means the dispensing of an opioid agonist treatment medication in decreasing doses to a patient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid and to bring the patient to a drug-free state.
9. "Department" means the North Dakota department of human services.
10. "Division" means the division of mental health and substance abuse services of the department.
11. "Division of pharmacologic therapies" means a division of the center, which manages the day-to-day regulatory oversight activities, including supporting the certification and accreditation of opioid treatment programs, necessary to implement title 42, Code of Federal Regulations, part 8, on the use of opioid agonist medications.
12. "Federal opioid treatment standards" means the standards in title 42, Code of Federal Regulations, part 8 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment and that set forth patient admission criteria.
13. "Health care professional" means a physician assistant or an advanced practice registered nurse working under the medical director's supervision.
14. "Long-term detoxification treatment" means detoxification treatment for longer than thirty days but not in excess of one hundred eighty days.
15. "Maintenance treatment" means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of thirty days in the treatment of an individual for opioid use disorder.
16. "Medical and rehabilitative services" means services, such as medical evaluations, counseling, and rehabilitative and other social programs such as vocational and educational guidance, and employment placement, intended to help a patient become and remain a productive member of society.

17. "Medical director" means a physician, licensed to practice medicine in the state, who assumes responsibility for administering all medical services performed by the opioid treatment program by whom the medical director is employed, either by performing the services directly or by delegating specific responsibility to authorized opioid treatment program physicians and health care professionals functioning under the medical director's direct supervision.
18. "Medication unit" means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private medical practitioners or pharmacists dispense or administer an opioid agonist treatment medication or collect biological specimen samples for drug testing or analysis.
19. "Opioid use disorder" reflects compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if another medical condition is present that requires opioid treatment, that are used in doses greatly in excess of the amount needed for that medical condition.
20. "Opioid agonist treatment medication" means any opioid agonist drug that is approved by the United States food and drug administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid use disorder.
21. "Opioid" means any drug with the natural derivative of opium or synthetic psychoactive substance similar to morphine with capability to create physical dependence.
22. "Opioid treatment" means the dispensing of an opioid agonist treatment medication, and the provision of a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological or physical effects of an opioid use disorder.
23. "Opioid treatment program" means a program engaged in opioid treatment, which is:
  - a. Certified as an opioid treatment program by the center;
  - b. Registered by the United States department of justice, drug enforcement administration under 21 U.S.C. section 823(g);
  - c. Accredited by an opioid treatment program accreditation body; and
  - d. Licensed as an opioid treatment program by the division.
24. "Patient" means an individual who undergoes treatment in an opioid treatment program.

25. "Program sponsor" means the person named in the application for certification under title 42, Code of Federal Regulations, part 8 as responsible for the operation of the opioid treatment program.
26. "Short-term detoxification treatment" means detoxification treatment for a period not in excess of thirty days.
27. "Treatment plan" means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-02. Requirements for opioid treatment program license - Application.**

1. An applicant for licensure to operate an opioid treatment program, must hold a current license in good standing, or be eligible and become licensed prior to operating an opioid treatment program, as a substance abuse treatment program under any of the following chapters: 75-09.1-02, 75-09.1-02.1, 75-09.1-03, 75-09.1-03.1, 75-09.1-04, 75-09.1-04.1, 75-09.1-05, 75-09.1-05.1, 75-09.1-06, 75-09.1-06.1, 75-09.1-07, or 75-09.1-07.1. Chapter 75-09.1-01 applies to this chapter with the following exceptions:
  - a. Section 75-09.1-01-20. Discharge and transfer criteria.
  - b. Section 75-09.1-01-25. Accreditation as a basis for licensing.
  - c. Section 75-09.1-01-26. Sanctions.
2. Prior to applying for a license to operate an opioid treatment program in this state, a prospective opioid treatment program provider shall provide documentation proving the need for an opioid treatment program in the specific area of the state being considered, and shall obtain written approval from the division to pursue licensure. The potential provider's documentation must include an assessment of the following criteria:
  - a. Whether other existing services and facilities of the type proposed are available or accessible to meet the needs of the population proposed to be served.
  - b. The extent to which the underserved need will be met adequately by the proposed program.

- c. The impact of the service on the ability of low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, and other underserved groups to obtain needed health care.
- 3. If the applicant is applying for licensure for the first time in this state, but operates an opioid treatment program in another state, the applicant shall submit a copy of national and state certification and accreditation documentation, and copies of all survey reports written by national and state certification and accreditation organizations for each site where they have operated an opioid treatment program over the past six years.
- 4. After receiving approval, the prospective opioid treatment program shall obtain:
  - a. Accreditation by an accreditation body.
  - b. Certification from the United States department of health and human services substance abuse and mental health services administration. An opioid treatment program that has applied to the administration for provisional certification while the opioid treatment program is working towards accreditation with an accrediting body may apply for licensure under this chapter.
  - c. Registration from the United States department of justice, drug enforcement administration, office of diversion control.
  - d. As determined necessary for any physician with the opioid treatment program, a data 2000 waiver for buprenorphine.
- 5. A potential opioid treatment program shall:
  - a. Submit documentation to the division showing the potential opioid treatment program provider has completed an assessment of need to determine there is a need for the proposed opioid treatment program as required under subsection 2.
  - b. Provide documentation ensuring the location for the new opioid treatment program meets county, tribal, or city land use ordinances.
  - c. Submit a completed community relations plan developed in consultation with the county, city, or tribal authority, or their designees, to minimize the impact of the opioid treatment program on the business and residential neighborhoods in which the program will be located. The plan must include documentation of strategies used to:
    - (1) Obtain community input regarding the proposed location;

- (2) Address any concerns identified by the community; and
    - (3) Develop an ongoing community relations plan to address new concerns expressed by the community as the concerns arise.
  - d. Submit a copy of the application for registration to the United States department of justice, drug enforcement administration.
  - e. Submit a copy of the application for certification to the center.
  - f. Submit a copy of the application for accreditation by an accreditation body.
  - g. Submit a plan describing reasonable transportation opportunities available to persons in need of treatment in their proposed service area to access the opioid treatment program.
  - h. Submit any additional information required by the division to assure the state and efficient operation of the facility.
6. An opioid treatment program shall enroll as an approved Medicaid provider in this state within ninety days of licensure under these rules.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-03. Denial of application for opioid treatment program license.**

- 1. The division shall deny an applicant's license:
  - a. When it fails to meet the requirements of section 75-09.1-10-02.
  - b. If the applicant has been denied, or has had revoked, the registration, accreditation, or certification required to be an opioid treatment program as set forth in subsection 22 of section 75-09.1-10-01.
  - c. If any of the following occurred and was not resolved at a facility under the control of the applicant:
    - (1) A license for a substance use disorder treatment service or health care agency was denied, revoked, or suspended in the past;
    - (2) Found to have discriminated against, demonstrated cruelty, abuse, negligence, or misconduct toward, or indifference to the welfare of, a patient;

- (3) Misappropriation of patient property or resources;
  - (4) Failed to meet financial obligations or contracted service commitments that affected patient care;
  - (5) Has a history of noncompliance with state or federal regulations in providing substance abuse treatment;
  - (6) Refused to allow the division access to records, files, books, or portions of the premises relating to operation of the substance abuse treatment program;
  - (7) Willfully interfered with the preservation of material information or attempted to impede the work of an authorized department representative;
  - (8) Advertised itself as licensed when a license has not been issued, or a license has been suspended or revoked; or
  - (9) Has not demonstrated the capability to provide the appropriate services to assist patients in meeting goals, including:
    - (a) Abstinence from opioids and opioid substitutes;
    - (b) Obtaining mental health treatment;
    - (c) Improving economic independence; and
    - (d) Reducing adverse consequences associated with illegal use of controlled substances.
- d. If an owner or administrator of a facility under the control of the applicant:
- (1) Has been convicted of child abuse or has been adjudicated as a perpetrator of child abuse;
  - (2) Has obtained or attempted to obtain a substance abuse treatment program license or health care provider license by fraudulent means or misrepresentation;
  - (3) Has been found guilty of, has pled guilty to, or has pled no contest to any of the offenses identified in paragraph 1 of subdivision c of subsection 1 of section 75-09.1-01-17;
  - (4) Has been found to have discriminated against, demonstrated cruelty, abuse, negligence, or misconduct toward, or indifference to the welfare of, a patient;

- (5) Has misappropriated patient property or resources;
- (6) Has failed to meet financial obligations or contracted service commitments that affect patient care;
- (7) Has knowingly, or with reason to know, made a false statement of fact in the application or materials attached to the application;
- (8) Has knowingly, or with reason to know, made a false statement of fact or failed to submit necessary information in any matter under investigation by the division; or
- (9) Does not meet criminal background check requirements.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-04. Issuing license to opioid treatment program.** The division shall issue a license after a review of application materials and an onsite visit confirms the applicant has the capacity to operate in compliance with this chapter. The division may issue an initial license for up to one year and subsequent licenses for up to two years.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-05. Suspension and revocation of license - Appeal.**

- 1. a. The division may suspend or revoke a license for one or more of the following reasons:
  - (1) The opioid treatment program has violated any of the opioid treatment program licensing rules;
  - (2) The opioid treatment program has procured any license through fraud or deceit;
  - (3) The department, or any other state agency, has revoked any other license issued to the opioid treatment program;
  - (4) Any principal of the opioid treatment program has been found guilty of, has pled guilty to, or has pled no contest to any of the offenses identified in paragraph 1 of subdivision c of subsection 1 of section 75-09.1-01-17;



- (5) The opioid treatment program has failed to report any important change in the information about a project as required;
  - (6) The opioid treatment program has failed to operate in accordance with the representations made in its application;
  - (7) The opioid treatment program has failed to operate in compliance with any applicable law, rule, or regulation;
  - (8) The opioid treatment program ceases to provide, or within one hundred eighty days from the date the license takes effect fails to commence to provide, the services it is authorized to provide.
- b. The division shall provide the opioid treatment program written notice of which of the following actions is being taken and the basis for that action:
  - (1) Revocation of the operating license, without which the opioid treatment program may no longer operate;
  - (2) Suspension of the operating license, during which time, the opioid treatment program may not continue its operations;
  - (3) Limitation placed on the license temporarily or permanently prohibiting the opioid treatment program from operating certain identified programs or services, reducing the number of beds, restricting the number or types of patients served or imposing any other limitation determined appropriate by the division.
- 2. If an inspection of the opioid treatment program identifies that an opioid treatment program is not in compliance with any of the licensure requirements set forth by the division, the division shall notify the opioid treatment program in writing of the deficiencies identified.
- 3. The opioid treatment program shall respond to the notification of deficiencies within the time the division sets forth in the notice. The opioid treatment program shall include in its response a plan for the correction of the identified deficiencies or an explanation for its deviation from licensure requirements.
- 4. If the opioid treatment program fails to correct deficiencies or fails to provide a sufficient explanation for its failure to take action, the division may suspend or revoke the opioid treatment program's license or may require other corrective measures from the opioid treatment program. The division shall notify the opioid treatment program in writing of the action being taken.

5. If there are reasonable grounds for the division to believe that continued operation of the opioid treatment program presents an immediate danger to the health and welfare of the public or any person receiving services, the division may immediately suspend a license.
6. An opioid treatment program may request a hearing regarding any suspension, revocation, or limitation as provided in section 75-09.1-01-27.
7. If a license is revoked, the division may consider a new application for a license if the conditions upon which the revocations were based have been corrected and evidence of the corrections has been provided. A new license may be issued after the division has inspected the opioid treatment program and has found that the applicant has complied with all requirements for licensure.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-06. Subsequent licensing inspection and review.** The division shall conduct licensure reviews of each licensed opioid treatment program at least once per year, with or without prior notice. The division shall inspect the opioid treatment program's services for compliance with all licensure requirements to determine the renewal term of the license. At the time of inspection, the opioid treatment program must have:

1. Maintained accreditation through an accreditation body;
2. Maintained certification from the administration;
3. Maintained registration with the United States department of justice, drug enforcement administration;
4. Maintained licensure as a substance abuse treatment program under any of the following chapters: 75-09.1-02, 75-09.1-02.1, 75-09.1-03, 75-09.1-03.1, 75-09.1-04, 75-09.1-04.1, 75-09.1-05, 75-09.1-05.1, 75-09.1-06, 75- 09.1-06.1, 75-09.1-07, and 75-09.1-07.1;
5. Must not have had any of the following occur without being resolved at a facility under the control of the applicant:
  - a. The facility's license for a substance abuse treatment program or health care agency denied, revoked, or suspended and was not reinstated without restrictions or limitations;
  - b. A finding that the facility discriminated against, demonstrated cruelty, abuse, negligence, or misconduct toward, or indifference to the welfare of, a patient;

- c. Misappropriation of patient property or resources;
  - d. Failure to meet financial obligations or contracted service commitments which affected patient care;
  - e. Noncompliance with state or federal regulations in providing substance abuse treatment;
  - f. Refusal to allow the division access to records, files, books, or portions of the premises relating to operation of the substance abuse treatment program;
  - g. Willful interference with the preservation of material information or attempt to impede the work of an authorized department representative;
  - h. The facility advertised itself as licensed when a license has not been issued, or a license has been suspended or revoked; or
  - i. Failure to demonstrate the capability to provide the appropriate services to assist patients in meeting goals, including:
    - (1) Abstinence from opioids and opioid substitutes;
    - (2) Obtaining mental health treatment;
    - (3) Improving economic independence; and
    - (4) Reducing adverse consequences associated with illegal use of controlled substances.
6. Must not have had an owner or administrator of a facility under the control of the applicant:
- a. Be convicted of child abuse or be adjudicated as a perpetrator of child abuse;
  - b. Has obtained or attempted to obtain a health care provider license or substance abuse treatment program license by fraudulent means or misrepresentation;
  - c. Found guilty of, plead guilty to, or plead no contest to any of the offenses identified in paragraph 1 of subdivision c of subsection 1 of section 75-09.1-01-17;
  - d. Found to have discriminated against, demonstrated cruelty, abuse, negligence, or misconduct toward, or indifference to the welfare of, a patient;

- e. Misappropriate patient property or resources;
- f. Fail to meet financial obligations or contracted service commitments in a way that affected patient care;
- g. Knowingly, or with reason to know, made a false statement of fact in the application or materials attached to the application;
- h. Knowingly, or with reason to know, made a false statement of fact or fail to submit necessary information in any matter under investigation by the division; or
- i. Not meet criminal background check requirements.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-07. Opioid treatment program requirements.** All licensed opioid treatment programs must comply with the following:

1. Patients must receive appropriate, comprehensive behavioral therapy from a licensed clinical professional, such as a licensed addiction counselor, a licensed independent clinical social worker, a licensed psychologist, or a licensed psychiatrist who is providing intervention beyond pharmacological management.
2. The opioid treatment program may continue medication-assisted treatment as long as the patient derives benefit from the treatment, desires to continue treatment and the physician or health care professional agrees to continue the treatment. A fixed length of time in treatment is not required as indefinite medication-assisted treatment may be clinically indicated. The medical director shall consider other medications during the course of treatment.
3. Federally approved pharmacological treatments for opioid addiction may be dispensed only by a licensed opioid treatment program.
4. The opioid treatment program shall establish comprehensive education and training requirements for physicians and other health care professionals, pharmacists, and licensed alcohol and drug abuse and behavioral health counselors affiliated with the opioid treatment program, which include relevant aspects of behavioral therapy and pharmacological treatment.
5. The opioid treatment program shall establish written rules of conduct for patients, which include a clear description of violations that may result in a patient's discharge from the treatment program. These rules

must require a patient to participate in urinalysis as the opioid treatment program may direct.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-08. Care of adolescents in opioid treatment program.** For a patient younger than eighteen years of age to be eligible for maintenance treatment in the opioid treatment program, the patient is required to have had two documented attempts at short-term detoxification treatment or drug-free treatment within a 12-month period. The program physician or other health care professional shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. A patient under eighteen years of age may not be admitted to a maintenance treatment program unless a parent, legal guardian, or other person authorized by law to consent to treatment for the patient completes and signs consent form, "Form FDA 2635 Consent to Methadone Treatment".

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-09. Treatment.**

1. The opioid treatment program shall ensure the clinical assessment of each patient takes into account the patient's history of opioid addiction.
2. At all stages of treatment. psychosocial and medical treatment must be of sufficient intensity and duration to be effective.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-10. Opioid treatment program administrative organization and responsibilities.**

1. Each opioid treatment program shall develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of behavioral difficulties, psychiatric comorbid conditions, medical complications, and communicable diseases that may be part of a patient's treatment needs. Any information exchanged across this network must facilitate treatment and protect patient privacy, consistent with the Health Insurance Portability and Accountability Act, and title 42, Code of Federal Regulations, part 2.

2. Each opioid treatment program shall create a written statement of its mission and goals for patient care.
3. An opioid treatment program shall maintain individualized personnel files as a record of employment. These files must contain employment and credentialing data, employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate training records.
4. An opioid treatment program shall require a criminal history record investigation as set forth under section 75-09.1-01-17 for an employee prior to allowing the employee to work with either adult or adolescent patients.
5. An opioid treatment program shall complete outcomes and data reports as requested by the division.
6. An opioid treatment program shall utilize the prescription drug monitoring program at least monthly for each patient.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-11. Facility and clinical environment.**

1. Each opioid treatment program shall ensure that its facility:
  - a. Has sufficient space and adequate equipment for the provision of services, including diagnosis, evaluation, and treatment of other medical, psychiatric, and behavioral disorders, if they are to be provided onsite.
  - b. Is clean and well-maintained.
2. Each opioid treatment program shall ensure protection of patient confidentiality, in accordance with federal and state confidentiality requirements.
3. The program sponsor is the responsible party and assumes responsibility for all of the opioid treatment program's employees, including a practitioner, agent, or other person providing medical, rehabilitative, or counseling services at the opioid treatment program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician in the position of medical director. An opioid treatment program shall submit a proposed change in its program sponsor to the division for approval at least sixty days prior to the effective date of the proposed change.

4. The medical director of an opioid treatment program is responsible for monitoring and supervising all medical services provided by the program. Only a licensed physician may serve as the medical director of an opioid treatment program. If there is a change in medical director, the opioid treatment program shall notify the division in writing within thirty days of the change.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

#### **75-09.1-10-12. Risk management.**

1. Each opioid treatment program shall:
  - a. Establish procedures to guard against critical incidents.
  - b. Provide a mechanism to address patient emergencies by establishing an emergency contact system, as appropriate within confidentiality requirements.
  - c. Ensure that there are staff members on duty who are trained and proficient in cardiopulmonary resuscitation, management of opioid overdose, medical emergencies, and other techniques as appropriate.
  - d. Establish and regularly update policies and procedures which address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, and other escalating and potentially dangerous situations, especially those in which security guards or police need to be summoned.
  - e. Shall provide information to patients on an ongoing basis, on the risks of discontinuing services, and on the potential consequences of using other substances.
  - f. Establish a policy on creation and use of individualized induction and dosing schedules for each patient.
  - g. Establish a policy for patients to take home medication for unsupervised use.
2. Each opioid treatment program shall create and maintain a plan for continuity of care for patients, including emergency procedures for obtaining access to medications in case of temporary program closure during service disruptions, such as those that may occur due to a major disaster or a more routine event, such as a snow storm. Each opioid treatment program shall develop and maintain an electronic database

consisting of client identification, emergency contact information, patient's current dose, last date medication administered, and number of take-home doses allowed as part of the patient's plan and must include a mechanism for informing each patient of the emergency arrangements. If there is a service disruption, the opioid treatment program shall implement its emergency plan and shall forward its database and plan to the division.

3. Each opioid treatment program shall:
  - a. Develop procedures for reporting critical incidents to appropriate opioid treatment program staff, to the facility's accrediting body, and to the division within twenty-four hours of the critical incident.
  - b. Establish procedures to ensure:
    - (1) Full documentation of each critical incident.
    - (2) Prompt investigation and review of the situation surrounding each critical incident.
    - (3) Implementation of timely and appropriate corrective action.
    - (4) Corrective actions are monitored until their effectiveness is assured.
    - (5) Medication is dispensed safely if a patient presents with concerning behavioral or medical signs and symptoms.
4. If a patient chooses to discontinue services against medical advice, the opioid treatment program shall explain the risks of discontinuing services and offer information about, and referral to, alternative treatment options.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-13. Opioid treatment program closures.** If an opioid treatment program closes involuntarily or voluntarily, the opioid treatment program shall:

1. Provide the division with a plan detailing procedures to ensure continuity of care for patients. The plan must include steps for the orderly transfer of patients, records, and assets to other programs or practitioners to:
  - a. Assure appropriate referral of patients to avoid disruption in patient care;
  - b. Preserve the confidentiality of patient records; and



- c. Ensure appropriate access to financial records and accounts.
2. The opioid treatment program shall notify the division of the anticipated closure at least ninety days prior to the closure, and identify the rationale for closure and the efforts to establish continuity of care for the patients. An opioid treatment program experiencing difficulties in maintaining its operations shall exercise due diligence to ensure patients have access to reasonable care upon the opioid treatment program's closure.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-14. Diversion control.** Each opioid treatment program shall develop:

1. A diversion control plan that demonstrates accountability to its patients and to the community. The diversion control plan should reflect the efficient use of personnel and other resources to achieve the highest quality of patient care, while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.
2. Each opioid treatment program shall inform its patients that diversion will be reported to law enforcement and the division and shall indicate how suspicions or evidence of diversion will be handled clinically. Each opioid treatment program shall establish clinical procedures to minimize diversion risk to ensure appropriate treatment, such as:
  - a. Routine toxicology screens;
  - b. Pill call backs for counting;
  - c. Bubble packing of prescriptions; and
  - d. Making copies of the identification numbers listed on the "strip" packaging to be available for call backs.
3. Each opioid treatment program shall:
  - a. Provide regular and continuous staff education.
  - b. Review program policies and procedures at least annually.

- c. Adhere to universal or standard infection control precautions promulgated by the centers for disease control and prevention.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08

**75-09.1-10-15. Medical and behavioral health standards.**

1. a. A physician or other health care professional for the opioid treatment program must diagnose opioid use disorder for an individual to be admitted for opioid treatment. The physician or other health care professional shall document or cosign the diagnosis, and admit each patient to maintenance treatment or detoxification treatment, as medically necessary. If pharmacological treatment is medically appropriate and prior to prescribing methadone, the physician or other health care professional shall assess whether it is appropriate to treat the patient with buprenorphine.
- b. An individual must have a one-year history of addiction to be admitted to a maintenance treatment program. An individual with less than a one-year history of dependence may be admitted to undergo detoxification treatment. The absence of current physiological dependence is not an exclusion criterion; admission is acceptable when clinically justified. An opioid treatment program may accept arrest and medical records, information from significant others and relatives, and other information as documentation of the one-year history of addiction.
- c. An opioid treatment program may waive the requirement that the individual have a one-year history of active addiction for an individual with a history of narcotic dependence who does not have current or active use, as a result of being released from a penal institution or having been previously treated.
- d. A physician or other health care professional shall assess and review assessment results with each patient before the patient is approved for treatment with an opioid agonist treatment medication. If the physician or other health care professional determines admission of an individual is an emergency, the physician or other health care professional may review a medical examination performed by another qualified health care professional to make the required diagnosis that would allow admission of the individual, provided the physician or other health care professional reviews and countersigns the patient record within seventy-two hours of the patient's admission. The physician or other health care professional would subsequently review the

assessment with the patient and discuss the medical services to be provided.

- e. An opioid treatment program shall make an intravenous drug injecting individual or a pregnant woman a priority when prioritizing individuals for admission.
2. At a minimum, an opioid treatment program shall provide each patient with the following:
- a. A comprehensive physical examination of the patient, including a review of health history, identification of other chronic or acute health conditions, current objective measures of health, pregnancy status of female patients, and laboratory work determined to be medically appropriate by a physician or other health care professional.
  - b. Based on the individual's history and physical examination, an evaluation of the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and possible concurrent surgical and other problems.
3. An opioid treatment program shall:
- a. Obtain voluntary, written, program-specific informed consent to treatment from each patient at admission, and written releases of information for all ancillary providers.
  - b. Inform each patient about all relevant treatment procedures and services and about other policies and regulations throughout the course of the patient's treatment.
  - c. Obtain, before medicating a patient, voluntary, written, informed consent from the patient to the specific pharmacotherapy ordered by the physician or other health care professional.
  - d. Inform each patient that:
    - (1) The goal of medication-assisted treatment is stabilizing of the patient's functioning.
    - (2) At periodic intervals of the patient's present level of functioning, course of treatment, and future goals, without placing pressure on the patient to withdraw from opioid agonist treatment medication or to remain on maintenance treatment unless the physician or other health care professional determines the proposed action to be medically indicated.

- e. Inform each patient, at admission, about specific requirements and program policies regarding the report of suspected child abuse and neglect, danger of harm to self or others or both, abuse or neglect of a vulnerable individual, and other behaviors having negative impact on the patient or others.
  - f. Adhere to all requirements of federal confidentiality regulations, including the Health Insurance Portability and Accountability Act (Public Law 104-191; 110 Stat. 1936).
4. a. The medical director or other health care professional of an opioid treatment program shall refer a patient for medical or psychiatric treatment when the medical director or other health care professional determines it to be appropriate.
- b. An opioid treatment program shall retain a patient in opioid treatment as long as treatment is clinically appropriate, medically necessary, acceptable to the patient, and the patient is considered to be adherent with the established rules of the program.
- c. (1) When a patient relocates, transfers to another treatment program, or needs temporary care at another program, the original opioid treatment program shall ensure the patient makes as smooth a transition as is feasible, and when possible shall avoid interruptions in treatment that could lead to relapse.
- (2) The original opioid treatment program shall forward relevant records to the receiving opioid treatment program, with patient consent in accordance with the privacy standards of title 42, Code of Federal Regulations, part 2.
- d. The opioid treatment program shall continue to provide psychosocial treatment for a patient who elects to discontinue pharmacotherapy. The opioid treatment program may continue to offer treatment, or referrals for continued psychosocial supports to patients as needed.
5. An opioid treatment program shall retain all records required by title 42, Code of Federal Regulations, part 8.12 for a minimum of seven years from the last date of service.
- a. An opioid treatment program is required under title 42, Code of Federal Regulations, part 8.11(f)(3) to comply with confidentiality requirements set forth under title 42, Code of Federal Regulations, part 2.
- b. A physician or other appropriate health care professional with the opioid treatment program shall write each medication order and

dosage change on an acceptable order sheet and shall sign the sheet.

- (1) Appropriate staff of the opioid treatment program shall make a record of each dosage the opioid treatment program dispenses, prepares, or receives and shall sign each entry to ensure a perpetual and accurate inventory of all medications and prescriptions, including controlled substances in stock at all times.
- (2) Appropriate staff of the opioid treatment program shall document clearly the patient's individual medication dose history, the time that each dose is administered or dispensed, and the identification of who administered or dispensed the medication.

6. a. A physician or other health care professional:

- (1) Who is with the opioid treatment program must be trained in the use of medication-assisted treatment to determine the individual dose of opioid medication for a patient.
- (2) Who is with the opioid treatment program shall provide opioid agonist treatment medication as clinically indicated, and shall assess the patient's ability to tolerate the medication and whether the patient suffers negative effects.
- (3) Who is with the opioid treatment program may not prescribe methadone on the first day it is administered to a patient in excess of thirty milligrams unless the physician documents a treatment need to prescribe an initial dose of forty milligrams.
- (4) As clinically appropriate, may prescribe the admission of a patient to an opioid treatment program for detoxification treatment. Detoxification treatment is conducted as a voluntary and therapeutic process, agreed on between physician or health care professional and patient using current best practices.

b. An opioid treatment program shall have a procedure for calibrating medication-dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking.

c. An opioid treatment program may not adjust medication doses to reinforce positive behavior or to punish negative behavior, unless the patient is noncompliant with programmatic expectations and the taper constitutes the start of a detoxification treatment or a dosage increase needed to address the patient's symptoms.

- d. The opioid treatment program should have the capability to obtain serum methadone levels when clinically indicated or urine-based buprenorphine or nor-buprenorphine levels.
- 7. An opioid treatment program shall take reasonable measures to prevent its patients from enrolling in treatment from more than one opioid treatment program.
- 8. a. If an opioid treatment program administratively discharges a patient from treatment using an opioid agonist treatment medication, the opioid treatment program shall offer a humane schedule of detoxification treatment, if clinically appropriate, provided doing so does not compromise the safety of staff or patients of the opioid treatment program.
- b. An opioid treatment provider may determine during the process of ongoing assessment that a patient is not appropriate for treatment through the opioid treatment program and may be better served by other treatment modalities. Specifically, if a patient continues to use substances, engages in medication diversion, or fails to respond to the treatment plan, the opioid treatment program may find the patient is not appropriate for treatment through its programming and may administratively discharge the patient.
- c. An opioid treatment program shall work with a patient to develop a plan of continuing care that includes discharge and recovery planning. An opioid treatment program shall ensure the discharge planning process includes procedures that address the patient's physical and mental health problems following detoxification treatment. The opioid treatment program shall include in the discharge plan, a plan for continuing care following the last dose of medication, including making a referral for continuing outpatient care as needed, and planning for reentry to maintenance treatment if relapse occurs and resumption of care continues to be appropriate.
- 9. Each opioid treatment program shall:
  - a. Use drug and alcohol screening and testing as aids in monitoring and evaluating patient's progress in treatment.
  - b. Ensure that treatment personnel in a medication-assisted treatment program understand the benefits and limitations of toxicological testing procedures.
  - c. Address results of toxicology testing with patients promptly.
  - d. Document in the patient record the results of toxicology tests and shall follow therapeutic interventions.

- e. Ensure compliance with all federal regulations related to urine toxicology results, title 42, Code of Federal Regulations, part 8.12(f). An opioid treatment program must provide adequate testing of or analysis for drugs of abuse according to best practices.
- f. For patients in short-term detoxification treatment, the opioid treatment program shall perform at least one initial drug abuse test.

**History:** Effective April 1, 2014.

**General Authority:** NDCC 50-31-08

**Law Implemented:** NDCC 50-31-08